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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/226,044	01/05/99	HOFFMAN	A UWS-102

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PATREA L. PABST
ARNALL GOLDEN & GREGORY
2800 ONE ATLANTIC CENTER
1201 PEACHTREE STREET
ATLANTA GA 30309-3450

EXAMINER
KISHORE, G

ART UNIT	PAPER NUMBER
1615	17

DATE MAILED: 10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/226,044

Applicant(s)
Hoffman

Examiner
Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 23, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 7-13, and 17-33 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7-13, and 17-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

The amendment filed on 7-23-01 is acknowledged.

Claims included in the prosecution are 1, 5, 7-13, and 17-33.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 1, 5, 7-13, and 17-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

It is unclear what the composition enhances the transport of as recited in claim 1. According to the Markush group, active agent need not be present at all.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant does not specifically address this issue. As pointed out above, one of the Markush group members includes a carrier. It is unclear as to the purpose of transporting a carrier without an active agent.

What is being conveyed by 'solvent to alter the solubility of the composition' as recited in claim 22? It is very confusing since the nature of the composition in claim 1 (parent claim) itself is unclear. What is this solvent?

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What is being conveyed by ‘esters of acrylic acid copolymerized with acrylic acid’ as recited in claim 28?

Where do the lysosome degrade and what is the compound which decreases the degradation as recited in claim 9? This rejection is maintained since the definition pointed out on page 27 discloses the compounds which minimize the lysosomal function such as enzyme inhibitors and not compounds which decrease the lysosomal degradation. Applicant further argues that “the compounds recited decrease the lisosomal degradation of a material in the lysosome ---”. This argument is not convincing since according to the claim these compounds are present as such in the composition and not linked to the polymer. It is common knowledge that any composition once administered, only dissipates and it is unclear how these compounds enter the lysosomes to decrease the acid production. Furthermore, as the examiner is aware, lysosomes contain acid hydrolases, meaning that these enzymes are active in acidic atmosphere once they are released by lysosomal rupture.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 5, 7, 9, 18,19, 21, 22, 28-29 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by Herbig (5,609,590).

Herbig discloses beads containing pH sensitive polymers and therapeutic agents (note the abstract, examples and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive.

The reference still meets the requirements of instant claims for the following reasons.

1) instant claim language does not exclude a device of Herbig; 2) according instant claim language, the carrier or therapeutic agent (second unit) is 'incorporated and in the reference the active agent within the the capsule which has the pH sensitive polymer; 3) the active agent is released at the desired site by pH trigger mechanism just as in instant case and the active agent enters the cells and naturally enhancing the transport of the active agent across the cell membrane (a therapeutic agent cannot act without penetration into the cell).

With regard to applicant's argument that there is no suggestion in Herbig of pH values of 5 and 6.5, the examiner points out that claim 1 does not recite any pH ranges. Secondly as

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pointed out before, the reference recites the same acrylic acid polymers and therefore, it is reasonable to assume that they have the same property with changes in pH.

Applicant's attention is once again directed to col. 8, line 45 through col. 9, line 10 where the reference teaches pH sensitive polymer. Furthermore, on col. 9, line 11, the reference teaches a blend of polymers which meets instant requirement of 'incorporated therein'.

5. Claims 1, 5, 7-13, and 18-33 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 97/09068 of record.

WO 09068 teaches stimuli-responsive polymer systems for drug delivery (note the abstract and the entire patent). The composition contains a the polymer chain which is responsive to changes in pH, temperature, light or other stimuli and a molecule such as a hormone or an enzyme (abstract, pages 10-27).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are on similar lines to those raised for the rejection over Herbig and hence same response is applicable. In essence, the reference teaches the same polymers responsive to stimuli on pages 10-21 and discloses the interactive compounds which are conjugated on page 22. The reference meets the requirements of instant claims.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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6. Claims 1, 5, 7, 9-10, 18-25 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Shapland (5,807,306).

Shapland discloses drug delivery using ultrasound or iontophoresis (note the abstract, column 16 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again are on similar lines to those raised for the rejection over Herbig and hence same response is applicable. In essence, Shapland discloses on col. 9, various polymers and propylene glycol which is incorporated within the matrix. Burden is upon applicant to show that these polymers do not have the intended functional limitation recited in claim 1. Propylene glycol meets the requirements of carrier recited in the claims. With regard to the pH ranges argued by applicant, the examiner points out that instant claims now recite no pH ranges.

7. Claims 1, 3, 5, 8-13, 17-19, 21-22, 27, 30 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Lishko (5,753,263).

Lishko teaches pH sensitive liposomal compositions containing a polymer or a synthetic peptide for the delivery of nucleic acids (note column 15, line 13 et seq., and col. 20).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again pertain to the lack of teachings of the pH

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sensitive polymers. Lishko teaches phospholipids, the carrier (instant claim 30) and the polymer taught by Lishko is pH sensitive as evident from col. 15.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1, 3, 5, 8-13, 17-19, 21-22, 27-31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lishko cited above.

As pointed out above, Lishko teaches pH sensitive liposomal compositions containing a polymer or a synthetic peptide for the delivery of nucleic acids (note column 15, line 13 et seq., and col. 20). Lishko however, does not specify the polymers and does not specifically disclose instant pH ranges. It would have been obvious to one of ordinary skill in the art that to select an appropriate polymer having a selected pH range sensitivity based on the teachings of Lishko with the expectation of obtaining the best possible results.

Applicant provides no specific arguments to this 103 rejection.

Applicant's general arguments with regard to this reference have been fully considered, but are not found to be persuasive. Applicant once again argues for the lack of teachings of a composition including a unit which enhances penetration of a lipid

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containing membrane such as a cell wall or a membrane around an endosome and that Lishko teaches away since Lishco teaches administering the drug to hair follicle which do not require the penetration of a lipid containing membrane. This argument is rather confusing since Hair follicular cells also contain a lipid membrane and instant claims do not exclude hair follicular cells.

NOTE: applicant provides arguments to Mitragitri. However, no rejection has been made over this reference.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

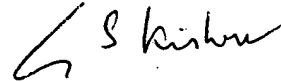
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

A handwritten signature in black ink, appearing to read "S Kishore", with a stylized flourish at the beginning.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600